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Food and Drug Administration
Washington DC 20204

WARNING LETTER

NOV 14 2000

Mr. Jesus Otero Diaz
Vice President/General Manager
AX Save, S.A. de C.V.
International Road KM 1589
Guasave, Sinaloa, Mexico 81122

Dear Mr. Diaz:

We inspected your firm, located at International Road KM 1589, Guasave, Sinaloa, Mexico on September 13 and 14, 2000 and found that you have serious deviations from the U.S. Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your pasteurized crabmeat and cooked ready-to-eat crabmeat to be in violation of section 402(a)(4) of the U.S. Federal Food, Drug, and Cosmetic Act. You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

Refrigerated Cooked Ready-to-Eat Crabmeat (Unpasteurized)

1. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor your employee practices with sufficient frequency to ensure control as evidenced by four employees with bandages on their hands handling your cooked, ready-to-eat crabmeat.
2. You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2).
 - Your firm's HACCP plan for Cooked Ready-to-Eat Crabmeat does not list the critical control points of Backing, Picking and Container Packing for controlling the food safety hazard of *Pathogen Growth*. According to your operating procedures, your picking and packing rooms are kept at 59 degrees Fahrenheit. Your crabmeat cannot be exposed to that temperature safely for more than 6 hours, cumulatively, between the first handling of the cooked crabs until final refrigeration of your packaged product.
 - Your firm's HACCP plan for Cooked Ready-to-Eat Crabmeat does not list the critical control point of Refrigerated Storage prior to shipment for controlling the food safety hazard of *Pathogen Growth*.

3. You must implement the monitoring procedures listed in your HACCP plan to comply with 21 CFR 123.6(b).
 - However, your firm did not follow the monitoring procedure of checking your cook temperature and pressure at your cooking critical control point to control the hazard of *Pathogen Survival through Cooking* listed in your HACCP plan for Cooked Ready-to-Eat Crabmeat. Your monitoring records show the cook time only. The temperature and pressure data was not recorded in your monitoring records for 8/17/00 and 8/18/00. In addition, your HACCP plan lists that you will record this information for each lot cooked. Your monitoring record lists several cook times and lots on each day's report, but has room for only one entry blank for the temperature and pressure data for that processing entire day.
 - However, your firm did not follow the monitoring frequency of checking your cooked crab cooling rooms each hour at the Cooling of Containers with Crabmeat critical control points to control the hazard of *Pathogen Growth* listed in your HACCP plan for Cooked Ready-to-Eat Crabmeat. Your monitoring records for August 25 and 28 have missing entries for several time periods.
 - However, your firm did not follow the monitoring frequency of checking the temperature of your cooked crabs each hour at the Cooling of Whole Crab critical control point to control the hazard of *Pathogen Growth* listed in your HACCP plan for Cooked Ready-to-Eat Crabmeat.

Pasteurized Cooked Crabmeat

1. You must implement the monitoring procedures listed in your HACCP plan, to comply with 21 CFR 123.6(b).
 - However, your firm did not follow the monitoring frequency of conducting a detailed seal evaluation on the metal containers used for every two hours of production at the Sealing critical control point to control the food safety hazard of *Pathogen Growth after Pasteurization* listed in your HACCP plan for Pasteurized Cooked Crabmeat.
 - However, your firm did not follow the monitoring procedure and frequency of checking the temperature and water chlorine concentration hourly at the Cooling after Pasteurization critical control point to control the food safety hazard of *Pathogen Growth after Pasteurization* listed in your HACCP plan for Pasteurized Cooked Crabmeat.

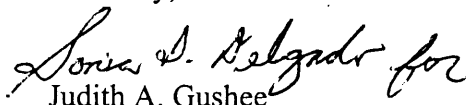
2. You must have a HACCP plan that lists the monitoring procedures that must be met, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for Pasteurized Cooked Crabmeat does not list the visual temperature monitoring frequency of your pasteurization process at the Pasteurization critical control point to control the food safety hazard of *Pathogen Survival through Pasteurization*. In addition to monitoring your pasteurization temperature continuously with a chart, you must also carry out a visual check of your procedure's temperatures. The frequency is based upon the type of process used and is outlined in Chapter 17 of the Fish & Fishery Products Hazards & Controls Guide.

Please respond in writing within six (6) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. If you believe the hazards listed above are not reasonably likely to occur in your products, you must provide U.S. FDA with adequate, written documentation that clearly supports your reasoning. You may wish to include in your response documentation such as corrected HACCP plans, completed monitoring records and other useful information that will assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations. Failure to provide us evidence of corrections to the deviations may result in your products being placed on "Detention Without Physical Examination."

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act; the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Brian Landesberg, Consumer Safety Officer, Office of Field Programs, Division of Enforcement and Programs, Import Branch, HFS-606, 200 C Street S.W., Washington, DC 20204. If you have questions regarding any issue in this letter, please contact Mr. Landesberg at (202) 205-5247.

Sincerely,

A handwritten signature in cursive script, appearing to read "Judith A. Gushee for".

Judith A. Gushee

Director

Division of Enforcement and Programs

Office of Field Programs

Center for Food Safety

and Applied Nutrition